## REFERENCES

- 1. 510(k) Manual Premarket Notification 510(k): Regulatory Requirements for Medical Devices, August 1995; http://www.fda.gov/cdrh/manual/510kprt1.html.
- 2. The New 510(k) Paradigm Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications; Final Guidance, March 20, 1998; http://www.fda.gov/cdrh/ode/parad510.html.
- 3. The Least Burdensome Provisions Activities Related to Implementation; http://www.fda.gov/cdrh/modact/leastburdensome.html.
- 4. Guidance Deciding When to Submit a 510(k) for a Change to an Existing Device, January 10, 1997; http://www.fda.gov/cdrh/ode/510kmod.html.
- 5. Guidance for Industry, Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods, January 2001; Technical Correction February 2001; http://www.fda.gov/cber/gdlns/rbcautoph2.htm.
- 6. Medical Device Reporting Guidance, Medical Device Reporting for Manufacturers, March 1997; http://www.fda.gov/cdrh/manual/mdrman.pdf.

2005 D- 0019

BKE 1